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| APPLICATION NO.          | FILING DATE                           | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|---------------------------------------|----------------------|---------------------|------------------|
| 10/772,398               | 02/06/2004                            | Toshio Matsumoto     | P24925 5023         |                  |
| 7055<br>GREENBLUM        | 7590 11/13/200<br>I & BERNSTEIN, P.L. |                      | EXAMINER .          |                  |
| 1950 ROLAND CLARKE PLACE |                                       |                      | LOPEZ, CARLOS N     |                  |
| RESTON, VA 20191         |                                       |                      | ART UNIT            | PAPER NUMBER     |
|                          |                                       |                      | 1791                |                  |
|                          |                                       |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                          |                                       |                      | 11/13/2007          | ELECTRONIC       |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|  |  | Application No.   | Applicant(s)  |  |  |  |
|--|--|---|---|--|--|--|
| Office Action Summary  |  | 10/772,398  | MATSUMOTO, TOSHIO                                     |  |  |  |
|  |  | Examiner  | Art Unit  |  |  |  |
|  |  | /Carlos Lopez/  | 1791  |  |  |  |
| Period fo  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |   |   |  |  |  |
| Status   |  |   |   |  |  |  |
| 2a)⊠   | Responsive to communication(s) filed on <u>04 September 2007</u> .  This action is <b>FINAL</b> .  2b) This action is non-final.   |   |   |  |  |  |
| 3)[_   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |   |  |  |  |
| Dispositi  | on of Claims   |   |   |  |  |  |
| <ul> <li>4)  Claim(s) 1-7 and 9-13 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-7 and 9-13 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>   |  |   |   |  |  |  |
| Applicati  | on Papers  |   |   |  |  |  |
| 10)⊠ ີ   | The specification is objected to by the Examiner The drawing(s) filed on <u>06 February 2004</u> is/are Applicant may not request that any objection to the o Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Example 1. | e: a)⊠ accepted or b)⊡ objecte<br>drawing(s) be held in abeyance. Se<br>ion is required if the drawing(s) is ob | e 37 CFR 1.85(a).<br>ejected to. See 37 CFR 1.121(d). |  |  |  |
| Priority u   | nder 35 U.S.C. § 119   |   |   |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No. 10/005,673.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |   |   |  |  |  |
| 2) Notice 3) Inform  | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date   | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:                                       | ate   |  |  |  |

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4, 7, 9,11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 63-40782 (782). '782 et al discloses a method of making porous ceramic sintered bodies. The method, as disclosed in example 1, comprises: 1) preparing a slurry comprising a calcium phosphate based ceramic powder, a deflocculating agent (deemed as the claimed water-soluble high molecular compound) and a foaming agent (deemed as the claimed nonionic surface active agent; (2) stirring said slurry vigorously to froth said slurry; and (3) solidifying the frothed slurry into a gel, and (4) drying and sintering said gel. It is noted that the deflocculating agent used in example one, is deemed as a polyacrylic acid, see page 2 of the certified translation, which as noted by applicant in page 7 of the specification can be used as a water-soluble high molecular compound.

'782 does not specifically disclose a degreasing step by heating the green block to temperature of 300 to 900°C. However, at page 6 of '782, the green block is first dried to a temperature of 40°C and then it is sintered by heating the green block to a temperature of 1000 to 1300°C at a rate of 300°C/hr. As the temperature is increased to its target sintering temperature, the green block is exposed to the claimed range of 300 to 900°C. Hence, it would be obvious to a person of ordinary skill in the art to have

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expected the claimed degreasing to occur in the process of '782 in view that the green block is exposed to the same claimed temperature range as applicant's green block.

Applicant is also referred to US 5,240,659 at Col. 6, lines 12ff showing degreasing is done at 700°C in order to remove any residual organic substances in the green block.

As for claim 2, the calcium phosphate used has a particle size of  $3\mu m$  or less, see example 1.

As for claims 4 and 12, see bridging paragraph of pages 5-6 noting the claimed fatty acid alkanolamide which encompasses the claimed oxide recited in claim 12.

As for claim 7 '782 does not disclose the claimed stirring conditions. However, in view that '782 stir the slurry to provide a froth, it would have been obvious to a person of ordinary skill in the art to have conducted routine experiments to determine the optimum stirring conditions

As for claim 9, '782 does not disclose the use of a foaming agent free of a metal ion or sulfate.

As for claim 11, page 1 of the certified translation notes of using a hydroxyapatite.

As for claim 13, see above noting drying prior to degreasing.

Claims 1, 3,4,7,9, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imura (GB 2348872) or alternatively over Imura (US 6,340,648). For citation purposes, the GB 2348870 patent will be used. Imura discloses a method of making a calcium phosphate porous sintered body as a substitute for bone or tooth

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material. The method, as disclosed in example 1, comprises: 1) preparing a slurry comprising hydroxyapatite, a cross-linking polymerizable organic compound (deemed as the claimed water-soluble high molecular compound) and a foaming agent (deemed as the claimed nonionic surface active agent; (2) stirring said slurry vigorously to froth said slurry; and (3) solidifying the frothed slurry into a gel, and (4) drying and sintering said gel.

Imura's GB and US patent do not disclose the claimed degreasing. However, example 1 discloses that after drying the green block, the block is then sintered at 1200°C. Hence, it would be obvious to a person of ordinary skill in the art to have expected the claimed degreasing to occur in the process of Imura in view that the green block would be exposed to the same claimed temperature range as applicant's green body.

Applicant is also referred to US 5,240,659 at Col. 6, lines 12ff showing degreasing is done at 700°C in order to remove any residual organic substances in the green block.

As for claim 3, page 10 of Imura notes using methyl cellulose as the cross-linking polymerizable organic compound.

As for claim 4, claim 7 of Imura notes using species of the claimed surface active agents.

As for claim 7, Imura does not disclose the claimed stirring conditions. However, in view that both Imura stirs the slurry to provide a froth, it would have been obvious to a

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person of ordinary skill in the art to have conducted routine experiments to determine the optimum stirring conditions

As for claim 9, Imura is silent disclosing a metal or sulfate group.

As for claim 11, see above noting the claimed hydroxyapatite.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imura (GB 2348872) or Imura (US 6,340,648) in view of JP 3-131580 ('580); or JP 63-40782 (782) in view of JP 3-131580 ('580). The British and US patent of Imura and JP '782 are silent disclosing the claimed % weight of the foaming agent (surface active agent), thickening agent (high molecular compound), and ceramic. However, JP '580 discloses the claimed %weight. In particular, example 1 of '580 notes of using 18-45% of a ceramic powder, .5% of foaming agent and .5% of a thickening agent to subsequently provide for a porous sintered ceramic body that can be used as a bone filler or material. At the time the invention was made it would have been obvious to a person of ordinary skill in the art to have used known compositions of foaming agents, thickening agents and ceramic as taught by '580 absent any indication by either Imura or '782 in order to make the desired porous ceramic sintered body used in synthetic bone material.

It is noted that claim 5 provides arbitrary wt%, thus .5% of 18%wt of ceramic is about 2 part of high molecular compound or surface active agent, assuming that the part by weight is based in the parts by weight of the ceramic. Meaning that the 18% by weight of ceramics is deemed as being 100part and the claimed parts by weight of the foaming and thickening agents are based, or relative to on the supplied ceramic

because claim 5 does specify if the part by weight is relative to the weight of the slurry or the supplied ceramic.

As for claim 6, as shown above adding the %wt of the thickener, ceramic and foaming agent results in a slurry being comprised of at least 19%wt of said components and up to 46%wt.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imura (GB 2348872) or Imura (US 6,340,648) in view of WO 98/15505 ('505); or JP 63-40782 (782) in view of WO 98/15505 ('505). The British and US patent of Imura and JP '782 are silent disclosing the claimed step of passing gas through the slurry of ceramics, foaming agent and thickener to forth the desired froth. However, '505 discloses a method of stirring the claimed slurry and introducing air to provide froth, see example 1 of '505 and subsequently form artificial body parts, bone.

At the time the invention was made it would have been obvious to a person of ordinary skill in the art to introduce air into the slurry of Imura or '782 as taught by '505 in order to promote froth formation.

It is clear from the disclosure of '505 that froth formation can be aided by the introduction of air, hence it would be obvious to a person of ordinary skill in the art to have done so in order to promote bubble formation as sought by Imura and '782.

### Response to Arguments

Applicant's arguments filed 9/4/07 have been fully considered but they are not persuasive. At page 8 of Applicant's response, it is argued that '782 does not disclose the claimed nonionic surfactant. However, fatty acid alkanolamide genus of '782

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disclosed in page 5-6, is deemed to encompass the claimed species oxide in view that the art already specifies that a type of fatty acid alkanolamide used in forming porous sintered bodies is N,N-dimethyldodecylamine oxide (See US 2007/0072009, paragraph 54). Hence, while '782 only discloses the genus fatty acid alkanolamide it is well understood in the art that it encompasses N,N-dimethyldodecylamine oxide species.

In regards to the arguments presented in pages 10-11, they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos Lopez whose telephone number is 571.272.1193. The examiner can normally be reached on Mon.-Fri. 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on 571.272.1189. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos Lopez/ Primary Examiner Art Unit 1791